K123892

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APR 0 5 2013

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared: March 20, 2013

Submitter: Mölnlycke Health Care US, LLC

5550 Peachtree Parkway, Suite 500

Norcross, GA 30092

Official Correspondent: Angela L. Bunn, RAC

Director, Regulatory Affairs of the Americas

Tel: 678-250-7930

Fax: 678-250-7981

e-mail: angela.bunn@molnlycke.com

Trade/Proprietary Name: Mepilex® Transfer Ag

Common Name: Wound and Burn Dressing

Classification Name: Dressing, Wound, Drug

Device Class: Unclassified

Product Code: FRO

Predicate Device Name(s): Mepilex® Border Ag

Description of Device:

Mepilex® Transfer Ag is a soft silicone wound contact layer that absorbs and transfers exudate, maintains a moist wound environment and has antimicrobial properties. A moist wound environment is shown to be beneficial for wound healing.

Mepilex® Transfer Ag contains silver sulphate which acts as a preservative to reduce or minimize growth of microorganisms within the dressing.

Mepilex® Transfer Ag has been shown to inactivate microorganisms for up to 14 days *in vitro*.

Mepilex® Transfer Ag consists of:

- a Safetac® adhesive layer
  - which is a unique and a patented adhesive technology
- a compressed polyurethane foam containing silver sulphate and activated carbon

Intended Use/Indication for Use:

Mepilex® Transfer Ag dressing is indicated for the management of a wide range of exuding wounds such as leg and foot ulcers, pressure ulcers, partial thickness burns, traumatic and surgical wounds. Mepilex® Transfer Ag can be used under compression bandaging.

***In vitro* Data:**

The following performance testing was completed on the proposed device:

- Antimicrobial effect against 16 stains
- Antimicrobial effect inside the dressing against P.a, S.a and C.a

All areas performed as expected to provide a level of efficacy deemed necessary for the intended use of this device.

Clinical Testing:

No clinical data was required.

Conclusion:

Based on the information presented in this submission, it can be concluded that the Mepilex® Transfer Ag is equivalent to the Mepilex® Border Ag (K100029) predicate with respect to intended use, materials, design, and technological characteristics. The only difference in the two materials is the removal of the backing film from the predicate device to the proposed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Mölnlycke Health Care US, LLC
% Angela L. Bunn, RAC
Director, Regulatory Affairs of the Americas
5550 Peachtree Parkway, Suite 500
Norcross, Georgia 30092

Letter dated: April 5, 2013

Re: K123892
Trade/Device Name: Mepilex® Transfer Ag
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 20, 2013
Received: February 25, 2013

Dear Ms. Bunn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K123892

Device Name: Mepilex® Transfer Ag

Indications For Use:

Mepilex® Transfer Ag dressing is indicated for the management of a wide range of exuding wounds such as leg and foot ulcers, pressure ulcers, partial thickness burns, traumatic and surgical wounds.

Mepilex® Transfer Ag can also be used under compression bandaging.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123892